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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,324	06/18/2001	Gregory F. Payne	8399-007-999	5267

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EDELL, SHAPIRO & FINNAN, LLC  
1901 RESEARCH BLVD  
SUITE 400  
ROCKVILLE, MD 20850-3164

EXAMINER
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KRASS, FREDERICK F

ART UNIT	PAPER NUMBER
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1614

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/22/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

09/763,324

Applicant(s)

PAYNE ET AL.

Examiner

Frederick Krass

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-28 and 35-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-28 and 35-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **Previous Rejections**

Unless specifically maintained infra, all previous rejections are withdrawn.

### **Scope of Enablement Rejection**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-28 and 35-43 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Initially solubilizing a chitosan polymer or oligomer before reaction, and then maintaining the reactivity-solubility-enzyme activity balance during homogenous phase reaction, is critical or essential to the practice of the invention, but not included in the claim(s). Accordingly, the claims in their current scope are not adequately enabled. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

To be enabling, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993). Explaining what is meant by "undue experimentation," the Federal Circuit has stated that

The test is not merely quantitative, since a considerable amount of

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experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPG v. Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996).

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence or absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art,
- 7) the predictability of the art; and
- 8) the breadth of the claims.

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. In re Fisher, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the Wands factors are relevant to the instant fact situation for the following reasons:

1. The nature of the invention, state and predictability of the art, and relative skill level

The invention relates to enzymatic chemical synthesis methods. The relative skill

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of those in the art is high, that of a PHD or PHD candidate. That factor is outweighed, however, by the unpredictable nature of the art.

The unpredictability of the art of enzymatic chemical synthesis is generally known. See, e.g., USP 5,340,483 at column 3, lines 45-58; as noted therein, the reactions involved are complex and involve the interaction of many different components. Because of this complexity, problems associated with the tyrosinase-catalyzed oxidation of phenols include slow synthesis times, precipitation of polymerized products, and inactivation of enzymes by reactive intermediates generated during synthesis. Accordingly, serious practical limitations placed on enzymatic synthesis have limited its use, even under very dilute conditions. See column 5, lines 5-33.

Applicant has overcome these inherent difficulties by conducting synthesis in homogenous phase solution. See the instant specification at page 10, lines 2-5, stating that "the present method avoids the problems with reaction rate and uniformity associated with heterogenous phase reactions in which an insoluble chitosan (as a powder, film or gel, for example) is used." Applicant does this by initially solubilizing the chitosan and then maintaining the reactivity-solubility-enzyme activity balance during the reaction. Specification at page 13, lines 17-32, and page 17, lines 20-24. This is not a mere optimization of reaction conditions; rather, it is a critical feature which is required to overcome the inherent disadvantages of enzymatic chemical synthesis and to practice the invention. (Once one has figured out how to overcome the inherent disadvantages of enzymatic chemical synthesis, determination of appropriate reaction conditions (such as temperature, concentration, etc.) then becomes a matter of optimization by routine experimentation, but not before).

2. The breadth of the claims

The claims as currently drafted are broad insofar as they are inclusive of methods in which the reactivity-solubility-enzyme activity balance is not maintained during reaction.

3. The amount of direction or guidance provided and the presence or absence of working examples

The specification does not provide any guidance for carrying out the claimed enzymatic syntheses without maintaining the reactivity-solubility enzyme activity balance. The working examples all carry out reactions under conditions in which this balance is maintained.

4. The quantity of experimentation necessary

Because of the known unpredictability of the art, and in the absence of experimental evidence, no one skilled in the art would accept the assertion that the instantly claimed methods (absent a positive recitation of maintaining the reactivity-solubility-enzyme activity balance) could be predictably used to enzymatically synthesize phenol-substituted chitosans. Accordingly, the instant claims do not comply with the enablement requirement of §112, since to practice the invention claimed in the patent a

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person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success.

5. Suggested Claim Language

Using claim 1 for illustration, the following amendment is proposed to place the claim in condition for allowance:

Claim 1. (Currently amended). A method of producing a modified chitosan polymer or oligomer, comprising reacting an enzyme with at least one phenolic compound in the presence of a chitosan polymer or oligomer in homogenous phase, said method comprising the steps of 1) solubilizing said chitosan polymer or oligomer and 2) reacting said oligomer and phenolic compound while maintaining a reactivity-solubility-enzyme activity balance effective to carry out said reaction in homogenous phase, thus producing an insolublized modified chitosan polymer or oligomer; and then solubilizing the modified chitosan polymer or oligomer.

Similar changes will be necessary in all other independent claims as well.

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### **Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick Krass whose telephone number is (571) 272-0580. The examiner can normally be reached on Monday through Friday from 9:30AM to 6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached at (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass  
Primary Examiner  
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